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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,840	03/06/2001	Thomas Specht	SCI 1781	5598

7590 05/20/2003

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EXAMINER

ZITOMER, STEPHANIE W

ART UNIT PAPER NUMBER

1634

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,840

Applicant(s)

SPECHT ET AL.

Examiner

Stephanie Zitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 34-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 25, 27-31 and 33-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 24, 26, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Application status

1. Receipt of the amendment and abstract filed February 19, 2003 is acknowledged.
2. Applicant has not complied with the following requirements:

Priority information

3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Other informalities

4. The disclosure is objected to because of the following informalities:
 - (a) All parts of the application must be in English. There are tables in German which appear to be duplicates of tables in English. The non-English tables should be deleted or rendered in English. It is advised that the voluminous tables be placed at the end of the specification rather than interrupting the text which make it difficult to read the latter.
 - (b) The correct sequence identifier is **SEQ ID NO:** or the plural **SEQ ID NOS:**.

Appropriate correction is required.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejection under 35 U.S.C. 101: Lack of utility

5. Claims 23, 24, 26, 39 and 40 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The claimed polypeptide partial sequences are not supported by a specific asserted utility because the disclosed use as "tools for finding active ingredients against the bladder tumor" (specification, page 7) is a general use in that other polypeptides and proteins as well as nucleic acids can be used in screening assays for bladder cancer drugs. In other words, the asserted utility

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is not specific to the claimed polypeptides. It would have been known to one of skill in the art to use the polypeptides to make antibodies and to use the antibodies to search for the full length proteins. However, this, too, is a generic utility which does not specifically apply to the claimed polypeptides in that it may be performed with any polypeptide. There can be no well-established utility for the polypeptides as the claimed sequences were not found in the prior art. Notably, the specification is directed to obtaining nucleotide sequences by computer alignment and manipulation of database sequences and the polypeptide sequences have been obtained by "assignment" (specification, page 132. Thus, the claimed subject matter has no substantial, i.e., no practical or "real world", utility.

6. Claims 23, 24, 26, 39 and 40 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Rejection under 35 U.S.C. 112, first paragraph: Lack of written description

7. Claims 23, 24, 26, 39 and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With exception of the claim 40 polypeptide, the claims appear to be drawn to a genus of polypeptide sequences that extend beyond the sequences disclosed in the specification including complete proteins and fusion polypeptides. However, no information as to the full length or fusion constructs of these sequences or other sequences encompassed by the claimed genus is provided. The specification only describes how the sequences may be "automatically lengthened" via computer program manipulations of database sequences (pages 131-132, Example 3). Regarding the claimed 80% and 90% homologous sequences of claims 24 and 26, the specification provides no information whatsoever as to which

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amino acids of the SEQ ID NO: sequences may be deleted or substituted nor even whether such homologous sequences would be required to have the same activity, if an activity were to be determined, as the claimed amino acid sequence. The new limitation to claims 24 and 26, "wherein said polypeptide is a PKC-potentiated inhibitory protein of PP1" is meaningless because the specification fails to provide any context or explanation or relationship to bladder tissue of this limitation. In addition to enablement the first paragraph of 112 requires a "written description". As set forth by the Court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. For all of the foregoing reasons, it is clear that applicant was not in possession of the claimed polypeptides and pharmaceutical agent at the time the application was filed.

Rejections under 35 U.S.C. 112, second paragraph: Indefiniteness

8. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 39 is confusing because "consisting essentially of" is not understood. It is not defined in the claims or in the specification such that one of ordinary skill in the art would not be apprised of the scope of the claimed invention.

Response to applicant's traversal

9. Applicant's arguments filed February 19, 2003 have been fully considered but they are not persuasive. The assertion that the nucleic acid, SEQ ID NO:121, encoding the claimed polypeptide is a "specific marker for human bladder cancer" (original emphasis) based on electronic Northern data is not supported by the specification. The data cited by applicant at page 143 (Table I) clearly show that the "gene" (*sic*) is down regulated in brain, stomach-esophagus and prostate tumor as well as in bladder tumor tissue. Furthermore, none of the tumor tissue types is identified (Northern analyses encompassed "all" tumors, page 12) such that it is unclear how the tumor data relate to

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one another if at all. Additionally, according to Table I, at least several other EST sequences, such as SEQ ID NOS:106, 11, 113, 123, 124, 125 selected at random, showed similar behavior in Northern. Therefore, based on the Northern data, applicant's assertion of "specific, substantial and credible use" (original emphasis) of the claimed polypeptide in diagnosis of bladder cancer via antibodies to the polypeptide is also unsupported. Regarding the new claim limitation, "PKC-potentiated inhibitory protein of PP1", the specification fails to describe the relevance of this putative activity to bladder cancer diagnosis.

Conclusion

10. No claim is allowed. The claims are free of the prior art.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is

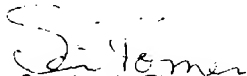
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(703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact LIE Chantae Dessau at 703-605-1237.


Stephanie Zitomer, Ph.D.

May 16, 2003

STEPHANIE W. ZITOMER
PRIMARY EXAMINER